FOOD AND DRUG ADMINISTRATION

Center for Drug Evaluation and Research

Oncologic Drugs Advisory Committee (ODAC)

AGENDA

February 8, 2011

The committee will hear updates on new drug applications (NDAs) and biologics license applications (BLAs) approved under 21 CFR 314.500 and 601.40 (subparts H and subpart E, respectively, accelerated approval regulations) prior to January 1, 2009. These updates will provide information related to the: (1) status of phase IV clinical studies; and (2) difficulties associated with completion of phase IV commitments. Phase IV studies are postmarketing studies to confirm clinical benefit of a drug after it receives accelerated approval.

Specifically, the committee will receive updates on the following products: (1) BLA 125084, trade name ERBITUX (cetuximab), application submitted by Imclone Systems Incorporated, used in combination with the anticancer agent irinotecan and indicated for the treatment of epidermal growth factor receptor (EGFR)-expressing colorectal cancer that has metastasized (spread beyond the colon or rectum) in patients for whom chemotherapy using irinotecan alone is ineffective or less effective; (2) supplemental BLA (sBLA) 125011/24, trade name BEXXAR (tositumomab and Iodine I 131 tositumomab), application submitted by SmithKline Beecham Corporation doing business as (d/b/a) GlaxoSmithKline, indicated for the treatment of patients with varieties of non-Hodgkin's lymphoma known as CD20 antigen-expressing relapsed or refractory, low grade, follicular, or transformed non-Hodgkin's lymphoma, who have not received the drug Rituximab; (3) NDA 21-673, tradename CLOLAR (clofarabine) for intravenous infusion, application submitted by Genzyme Corporation, indicated for the treatment of pediatric patients 1 to 21 years old with acute lymphoblastic leukemia (ALL) whose disease has not responded to or has relapsed following treatment with at least two prior chemotherapy regimens; (4) NDA 21-877, tradename ARRANON (nelarabine) Injection, application submitted by GlaxoSmithKline, indicated for the treatment of patients with types of leukemia or lymphoma known as T-cell acute lymphoblastic leukemia and T-cell lymphoblastic lymphoma whose disease has not responded to or has relapsed following treatment with at least two chemotherapy regimens; (5) BLA 125147, tradename VECTIBIX (panitumumab), application submitted by Amgen, Incorporated, indicated for the treatment of EGFR-expressing, metastatic colorectal carcinoma with disease progression on or following fluoropyrimidine-, oxaliplatin-, and irinotecan-containing chemotherapy regimens; and (6) sNDA 21-588/025, tradename GLEEVEC (imatinib mesylate) tablets, application submitted by Novartis Pharmaceuticals Corporation, indicated for the adjuvant (additional) treatment of adult patients following complete gross resection (removal) of a form of cancer known as Kit (CD117) positive gastrointestinal stromal tumors (GIST).

Based on the updates provided, the committee will have a general discussion centering on possible ways to improve the planning and conduct of trials to confirm clinical benefit (post marketing requirements). The overall goal will be the optimization of the accelerated approval process with a focus on decreasing the amount of time to confirm (or fail to confirm) clinical benefit while continuing to provide early availability of promising oncology products.

8:00 a.m.	Call to Order Introduction of Committee	**Wyndham Wilson, M.D., Ph.D.** Chair, ODAC
	Conflict of Interest Statement	**Nicole Vesely, Pharm.D.** Designated Federal Officer, ODAC
8:10 a.m.	Opening Remarks	**Richard Pazdur, M.D.** Director, Office of Oncology Drug Products (OODP), Office of New Drugs (OND), CDER, FDA
8:15 a.m.	**FDA Presentation** Accelerated Approval (AA) for Oncology Drug Products: An Update and Regulatory Overview	**Paul Kluetz, M.D.** Medical Officer, Division of Drug Oncology Products

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8:45 a.m.	**FDA Presentation** Accelerated Approval Overview of HIV Drug Approvals	**Jeff Murray, M.D., M.P.H.** Deputy Director, Division of Antiviral Products
9:00 a.m.	**Sponsor Presentation** Erbitux (cetuximab): Erbitux in the treatment of metastatic colorectal carcinoma (mCRC)	**Eli Lilly and Co. – Erbitux** **Colleen Mockbee, Pharm.D.** Senior Director, Regulatory Affairs Eli Lilly & Company
9:15 a.m.	Questions from Committee to Sponsor	
9:30 a.m.	*Break*	
9:35 a.m.	**Sponsor Presentation** Bexxar Therapeutic Regimen (Tositumomab and Iodine I 131 Tositumomab) Post-marketing Commitments	**GlaxoSmithKline – Bexxar** Thomas S. Lin, M.D., Ph.D. Director, Clinical Development GSK Oncology
9:50 a.m.	Questions from Committee to Sponsor	
10:05 a.m.	*Break*	
10:10 am	**Sponsor Presentation** Clolar® (clofarabine) Pediatric Relapsed/Refractory Acute Lymphoblastic Leukemia	**Genzyme Corp. – Clolar** **Mark Hayes, Ph.D.** Group Vice President Genzyme Regulatory Affairs
10:25 a.m.	Questions from Committee to Sponsor	
10:40 a.m.	*Break*	
10:50 a.m.	**Sponsor Presentation** Arranon (nelarabine) Injection Accelerated Approval Update	**GlaxoSmithKline – Arranon** **Mark Russo, M.D., Ph.D.** GSK
11:05 a.m.	Questions from Committee to Sponsor	
11:20 a.m.	*Break*	
11:25 am	**Sponsor Presentation** Vectibix®(panitumumab) Accelerated Approval Status	**Amgen, Inc. – Vectibix** **Paul Eisenberg, M.D., M.P.H.** Global Regulatory Affairs & Safety, Amgen, Inc.
11:40 a.m.	Questions from Committee to Sponsor	

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11:55 a.m.	*Break*	
12:00 noon	**Sponsor Presentation** Gleevec Adjuvant GIST Accelerated Approval ODAC	**Novartis Pharmaceuticals Corp. – Gleevec** **Laurie Letvak, M.D.** Vice President, Global Program Head Novartis Pharmaceuticals Corp.
12:15 p.m.	Questions from Committee to Sponsor	
12:30 pm	*Lunch*	
1:30 pm	**Speaker Presentation** Conditional Marketing Authorisations in the European Union (EU)	**Hilde Boone, Pharm, MSc (Guest Speaker)** European Medicines Agency Liaison Official at the US FDA
1:45 pm	Open Public Hearing	
2:45 pm	Questions to the ODAC and ODAC Discussion	
3:45 pm	*Break*	
4:00 pm	Questions to the ODAC and ODAC Discussion (continued)	
5:00 pm	*Adjourn*	